K091583

[redacted]

MEDEFIL, INC.

JAN 28 2010

"Continuous improvement today for the challenges of tomorrow"

510(k) Summary

MEDEFIL'S NORMAL SALINE I. V. FLUSH SYRINGE

JANUARY 27, 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

1. Reason for 510(k): Introduction of a terminally sterilized product

2. Name of Device:

Classification Name	Catheter Intravascular, Small Volume
Common Name	0.9% Sodium Chloride Injection, USP.
Proprietary Name	Medefil's Normal Saline I. V. Flush Syringe

3. Classification:

Name/Class	21 CFR 880.5200 Class II
Panel	General Hospital
Product Code	NGT

4. Establishment Registration Number: 1423982

5. Submitter's Name and Address:

Medefil, Inc.
250 Windy Point Drive
Glendale Heights, Illinois 60139

6. Manufacturing and sterilization facilities:

Medefil, Inc.
250 Windy Point Drive
Glendale Heights, Illinois 60139

7. Performance Standards:

No performance standard(s) applicable to this device has been promulgated under Section 514 of the Food, Drug, and Cosmetic Act.

7. Device Description and Indicated Use:

The DEVICE, the subject of this 510(k), Normal Saline I. V. Flush Syringes (0.9% Sodium Chloride Injection, USP) will be terminally sterilized as compared to its predicate device which was aseptically filled. The DEVICE will be marketed in various sizes and fill volumes similar to its predicate device.

Same intended use as the Predicate Device

For use to maintain the patency of in-dwelling intravenous vascular access device (IVAD).

8. Packaging:

Same packaging as the Predicate Device

The DEVICE provided is individually packaged in a plastic pouch (dust cover).

The DEVICE shall be pyrogen free per the LAL test method for bacterial endotoxin.

9. Substantial Equivalence:

The Normal Saline Flush Syringe DEVICE is substantially equivalent to the legally marketed predicate device listed below:

Medefil, Inc.
Normal Saline I. V. Flush Syringe
(K020999)

The proposed modification involves change in the polypropylene and sterilization process.

END OF SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 28 2010

Mr. Pradeep Aggarwal
President and Chief Executive Officer
Medefil, Incorporated
250 Windy Point Drive
Glendale Heights, Illinois 60139

Re: K091583
Trade/Device Name: Normal Saline I.V. Flush Syringe
Regulation Number: 21CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: NGT
Dated: January 25, 2010
Received: January 26, 2010

Dear Mr. Aggarwal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K091583

Device Name: NORMAL SALINE I. V. FLUSH SYRINGE

Model Number	Concentration	Fill Volume
MIS-1121	9 mg/mL	1 mL fill in 6 mL Syringe
MIS-1122	9 mg/mL	2 mL fill in 6 mL Syringe
MIS-1152	9 mg/mL	2.5 mL fill in 6 mL Syringe
MIS-1123	9 mg/mL	3 mL fill in 6 mL Syringe
MIS-1125	9 mg/mL	5 mL fill in 6 mL Syringe
MIS-1133	9 mg/mL	3 mL fill in 12 mL Syringe
MIS-1135	9 mg/mL	5 mL fill in 12 mL Syringe
MIS-1130	9 mg/mL	10 mL fill in 12 mL Syringe

Indications For Use:

FOR USE TO MAINTAIN THE PATENCY OF IN–DWELLING INTRAVENOUS VASCULAR ACCESS DEVICES (IVAD)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elaine S. Morhall for EFC

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091583